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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,687	07/03/2001	Henry J. Pepin	1001.1458101	1767

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/898,687	Applicant(s) PEPIN, HENRY J.	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 December 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6,8</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,2,8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,019,057 to Truckai.

Figures 1 and 3 of Truckai most clearly illustrate the claimed invention. The catheter includes an inner layer (12), braided wire reinforcement layer (16), and outer layer (22). A first wire (18b) is wound in a first direction and a second wire of smaller diameter (24) is wound in the opposite direction. In line 26 of column 4, Truckai explains that the wires are made of steel, which well known in the art to be radiopaque. Since stainless steel is more radiopaque than some materials, such as nitinol, it is considered to meet the limitation of *highly* radiopaque.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1,2,4-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,068,622 to Sater et al. in view of U.S. Patent No. 5,019,057 to Truckai.

Sater includes all the limitations of claims 1-18, but fails to form the diameter of one pair of wires smaller than the diameter of another pair of wires. In Figure 5, Sater does disclose a "two-over-two" braid pattern (Figure 5), with parallel and adjacent wires having equal diameters. Truckai teaches that filaments wound in opposite directions may be of differing diameters, Figure 3, as this structure improves torsional stiffness. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form a pair of wires Sater to have a smaller diameter than an opposing pair of wires, as taught by Truckai, as this structures improves physical properties of the catheter.

Sater includes an inner layer (125), outer layer (130), and braided reinforcement layer (135), as best shown in Figure 4. Sater explains that the catheter has *graduated distally increasing flexibility* (column 4, paragraph 4 and column 6, paragraph 5). The highly flexible distal tip is formed only of the polymer layer, and is un-reinforced (column 6, line 65). The braided wires are formed of stainless steel (column 7, line 39), which is inherently radiopaque. Sater also explains that the catheter device is sized to pass through vasculature (column 6, line 35).

3. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai in view of US Patent No. 6,165,163 to Chien et al.

Truckai includes all the limitations of claims 19 and 20, but fails to form the wires of the braided catheter from a material that comprises tungsten. Chien discloses a braided catheter that has ribbons made of stainless steel (column 13, line 30). Chien

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teaches that tungsten alloys can be used as a substitute for the stainless steel ribbons (column 13, line 31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the wires of Truckai from tungsten alloys, as taught by Chien, as this material is simply a substitute for stainless steel.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Truckai in view of Sater, as applied to claim 14 above, and further in view of Chien.

Truckai, as modified by Sater above, includes all the limitations of claim 21, but fails to form the wires of the catheter from a material that comprises tungsten. Chien discloses a braided catheter that has ribbons made of stainless steel (column 13, line 30). Chien teaches that tungsten alloys can be used as a substitute for the stainless steel wires (column 13, line 31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the wires of the modified Truckai catheter from tungsten alloys, as taught by Chien, as this material is simply a substitute for stainless steel.

Response to Arguments

5. Applicant's arguments filed 12/12/02 have been fully considered but they are not persuasive. Applicant argues in Paper No. 7 that the references used in the rejection fail to include a *highly* radiopaque material. The specification does not provide a complete list of *highly* radiopaque metals or a clear definition of *highly* radiopaque. A definition of the dividing line between high, medium, and low radiopacity was not provided. Stainless steel is well known in the art to be a radiopaque material, and is more radiopaque than many materials. A reference from Jomed states that nitinol is less radiopaque than stainless steel (page 5). Granted, stainless steel is not as

radiopaque as some materials, such as tungsten, but that does not mean stainless steel does not fall within the category of “highly radiopaque”.

Many references provide support that stainless steel is well known in the art to be a good radiopaque material. Samson (US 6096055) suggests that stainless steel is just as suitable in radiopacity as a tungsten alloy (column 4, lines 55-57). Krutten explains that it is desirable to form a radiopaque strip in a catheter of steel (column 1, line 65). A reference from Devon Medical states that a stent made from Stainless Steel has “very good” radiopacity (page 2).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb
Examiner
Art Unit 3731

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February 24, 2003

Michael Milano
Supervisory Patent Examiner
Art Unit 3700